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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,753	PIZZA, MARIAGRAZIA	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26, 28-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending.

Claim 27 is drawn to a non-statutory invention under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Consequently, only claims 1-26 and 28-31 are included in the restriction requirement set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2-3 and 26, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B.

Group II, claim(s) 4-14, and 26, drawn to a composition comprising NadA protein, 741 protein, 953 protein, and 287 protein.

Group III, claim(s) 15, drawn to a composition comprising NadA protein, 741 protein, 953 protein, and 287 protein, wherein at least two of the antigens are in the form of a single fusion protein.

Group IV, claim(s) 16-19, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, comprising a fusion protein, where the fusion protein consists of NadA and 741, NadA and 936, NadA and 953, NadA and 287, 741 and 953, 741 and 287, 936 and 953, 936 and 287, or 953 and 287.

Group V, claim(s) 20, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N.*

meningitidis serogroup B, wherein the composition comprises a protein comprising SEQ ID NO:7.

Group VI, claim(s) 21, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein the composition comprises a protein comprising SEQ ID NO:8.

Group VII, claim(s) 22, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein said composition additionally comprises saccharide antigens from meningococcus serogroups Y, W135, C, and (optionally) A.

Group VIII, claim(s) 23, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein said composition additionally comprises a saccharide antigen from *Haemophilus influenzae* type B.

Group IX, claim(s) 24, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein said composition additionally comprises saccharide antigens from meningococcus serogroups Y, W135, C, and (optionally) A, and wherein the saccharide antigens are conjugated to a carrier.

Group X, claim(s) 24, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein said composition additionally comprises a saccharide antigen from *Haemophilus influenzae* type B, and wherein the saccharide antigen is conjugated to a carrier.

Group XI, claim(s) 25, drawn to a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B, wherein said composition additionally comprises an antigen from *Streptococcus pneumoniae*.

Group XII, claim(s) 28, drawn to a method of raising an antibody response in a mammal by administering a composition able to induce an antibody response that is bactericidal against 2 or more of hypervirulent lineages A4, ET-5, and lineage 3 of *N. meningitidis* serogroup B.

Group XIII, claim(s) 28, drawn to a method of raising an antibody response in a mammal by administering a composition comprising NadA protein, 741 protein, 953 protein, and 287 protein.

Group XIV, claim(s) 29, drawn to a polypeptide having the amino acid sequence of SEQ ID NO:X.

Group XV, claim(s) 30, drawn to a method of purifying soluble NadA from a culture medium.

Group XVI, claim(s) 31, drawn to a method of purifying a 936-ΔG741 hybrid protein from a bacterium.

Claim 1 links Inventions I and IV-IX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Antigen Election Requirement Applicable to Groups III, IV, VII, and XIV

In addition, Groups III, IV, VII, and XIV, detailed above, read on patentably distinct antigens. Each antigen is patentably distinct because they are proteins or antigens with differing biochemical and immunological properties and a further restriction is applied to each Group. Applicant must further elect:

For Group III, choose the antigens in the fusion protein.

For Group IV, choose the antigens in the fusion protein.

For Group VII, choose the serogroup from which the saccharide antigen comes.

For Group XIV, choose a single SEQ ID NO.

Applicant is advised that examination will be restricted to only the elected antigen(s) and should not be construed as a species election.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

There is no special technical feature linking the groups. For example, group XVI is drawn to a method of purifying a 936-ΔG741 hybrid protein from a bacterium, whereas none of the other groups are drawn to a 936-ΔG741 hybrid protein.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian Gangle
AU 1645

ROBERT A. ZEMAN
PRIMARY EXAMINER